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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06 — A1

(11) International Publication Number: **WO 95/21592**

(43) International Publication Date: 17 August 1995 (17.08.95)

(21) International Application Number: PCT/US95/01466

(22) International Filing Date: 6 February 1995 (06.02.95)

(30) Priority Data:

94400284.9	9 February 1994 (09.02.94)	EP
(34) Countries for which the regional or international application was filed:		GB et al.
94401306.9	10 June 1994 (10.06.94)	EP
(34) Countries for which the regional or international application was filed:		GB et al.
08/312,881	27 September 1994 (27.09.94)	US
08/317,763	4 October 1994 (04.10.94)	US

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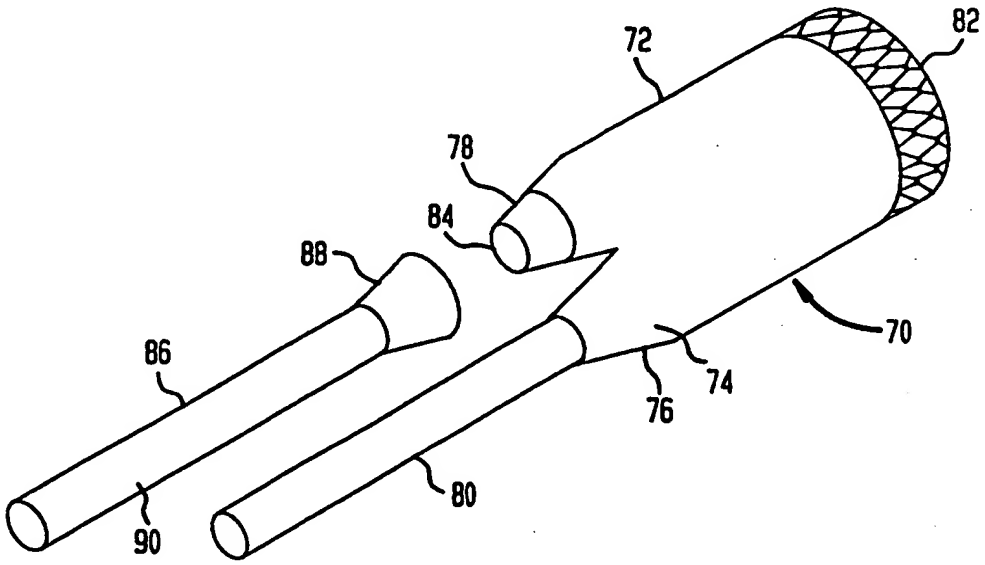
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: BIFURCATED ENDOLUMINAL PROSTHESIS



(57) Abstract

The invention comprises: an introducer for delivering into the vasculature a straight or bifurcated stent or prosthesis; a method for delivering into the vasculature a straight or bifurcated stent or prosthesis; a method of treating an angeological disease using a bifurcated stent; an endoluminal stent having perpendicular hoop members, each hoop member formed of wire in a sinuous configuration, at least some of juxtaposed apices in neighboring hoops being secured to one another, such stents also forming axially aligned segments in straight stents, and segments of bifurcated stents in particular embodiments. Certain embodiments of such stents also include barbs, fabric covering and radiopaque markers.

BIFURCATED ENDOLUMINAL PROSTHESIS

BACKGROUND OF THE INVENTION

The present invention relates to a bifurcated endoluminal prosthesis for use in a bifurcated blood vessel such, for example, as the infrarenal portion of a mammalian aortic artery where it bifurcates to the common iliac arteries. The present invention also embraces a stent connecting means for connecting a stent (e.g. a stent which forms part of an endoluminal prosthesis) to another stent, as well as apparatus and method for introducing prostheses to the vasculature and methods of treating angeological diseases.

A stent is used to provide a prosthetic intraluminal wall e.g. in the case of a stenosis to provide an unobstructed conduit for blood in the area of the stenosis. An endoluminal prosthesis comprises a stent which carries a prosthetic graft layer of fabric and is used e.g. to treat an aneurysm by removing the pressure on a weakened part of an artery so as to reduce the risk of embolism, or of the natural artery wall bursting. Typically, a stent or endoluminal prosthesis is implanted in a blood vessel at the site of a stenosis or aneurysm by so-called "minimally invasive techniques" in which the stent is compressed radially inwards and is delivered by a catheter to the site where it is required through the patient's skin or by a "cut down" technique in which the blood vessel concerned is exposed by minor surgical means. When the stent is positioned at the correct location, the catheter is withdrawn and the stent is caused or allowed to re-expand to a predetermined diameter in the vessel.

U.S. Patent 4,886,062 discloses a vascular stent which comprises a length of sinuous or "zig-zag" wire formed

desirable to avoid surgery wherever possible; the requirement for by-pass surgery associated with the use of the prior art prosthesis in juxtaposition with a bifurcation in an artery therefore constitutes a significant disadvantage.

SUMMARY OF THE INVENTION

Throughout this specification, the term "proximal" shall mean "nearest to the heart," and the term "distal" shall mean "furthest from the heart."

According to one aspect of the present invention there is provided a stent connecting means for connecting two intraluminal stents one to the other to define a continuous lumen through the two stents, the stent connecting means including a first stent including a male engaging portion which can be compressed radially inwardly, and a second stent including a female cooperating portion. The male engaging portion may be entered into the female cooperating portion in a radially compressed state and thereafter caused or allowed to expand in the female cooperating portion; the arrangement being such that in service the interengagement of the male engaging portion and the female cooperating portion serves to resist longitudinal separation of the two stents one from the other.

Typically, the first stent may include a proximal male engaging portion; the second stent may include a distal female cooperation portion. The male engaging portion may be flared radially outwardly towards its extremity, and the female cooperating portion may be tapered radially inwardly towards its extremity. In some embodiments, the male engaging portion may comprise a frustoconical wall which flares outwardly towards its longitudinal extremity; the female engaging portion may comprise a frustoconical wall which tapers radially inwardly towards its longitudinal extremity.

Alternatively, said male engaging and female cooperating portions may be substantially untapered; they may be substantially cylindrical.

flow from the proximal portion into the other branched vessel. The first distal stent portion may be formed integrally with the proximal portion.

In some embodiments the second distal stent portion may comprise a female cooperating portion which is adapted to engage a male engaging portion of a another stent adapted to extend in the other branched blood vessel such that, in use, the bifurcated stent can be connected in situ to the other stent. The bifurcated intraluminal stent may therefore constitute a second stent in accordance with the present invention comprising a distal female cooperating portion disposed intermediate the proximal and distal extremities of the stent; the other stent may constitute a first stent in accordance with the present invention.

Typically, the proximal end of said second stent may be flared radially outwardly towards its extremity to engage the endoluminal surface of the artery thereby to resist longitudinal movement of the second stent in service.

Each of the first and second stents may comprise a sinuous wire formed into a tubular configuration. The sinuous and tubular configurations may be imparted to the wire by winding it on a mandrel. Typically, each stent may be made from a shape memory nitinol (nickel~titanium) wire which may be wound on to the mandrel to form the stent in a tubular configuration of slightly greater diameter than the diameter of the blood vessel in which the stent is intended to be used. The stent may be annealed at an elevated temperature and then allowed to cool in air so that the nitinol wire "remembers" the configuration in which it was wound on the mandrel.

Said nitinol wire may be type "M" nitinol wire which is martensitic at temperatures below about 13°C and is austenitic at temperatures above about 25°C; it will be appreciated therefore that the type "M" wire will be austenitic at body temperature of 37°C. Typically, the annealing may be conducted at about 500°C or more for at least about 60 minutes; after cooling the wire may be immersed in cold water to facilitate removal of the wire from the mandrel

Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together; the loop element may also comprise a loop formed of a thermoplastics material such, for example, as polypropylene. Alternatively, the securing means may be a bead formed of a thermoplastic material around juxtaposed apices. Also alternatively, the securing means may be a loop, ring, or staple formed of wire such as nitinol.

The male engaging portion and female cooperating portion, of the first and second interengaging stents of this invention, may be formed separately from the remainder of the respective non-engaging portions of these stents and then the engaging and non-engaging portions secured to one another by securing means.

In one embodiment of the present invention, the proximal and distal stent portions of the bifurcated stent in accordance with the present invention may be formed separately; the distal end of the proximal stent portion may be secured to the wider proximal end of a first intermediate frustoconical stent portion; the narrower distal end of the first intermediate frustoconical stent portion may be secured to the proximal end of the distal stent portion. The female cooperating portion of the bifurcated stent may be constituted by a second frustoconical stent portion which is secured to the distal end of the proximal stent portion in juxtaposition with the first frustoconical portion.

Alternatively the first and second frustoconical portions may be omitted; the proximal and distal stent portions may be secured directly one to the other.

The female cooperating portion may be constituted by a generally cylindrical stent portion secured to said proximal stent portion in transversely spaced relation to the distal portion.

portion engages in the female cooperating portion to resist longitudinal separation of the two prosthesis in service.

The bifurcated prosthesis may be adapted for use in the infrarenal portion of a mammalian aorta in juxtaposition with the bifurcation of the common iliac arteries for the treatment of abdominal aortic aneurysms. In use the bifurcated endoluminal prosthesis may be introduced into the infrarenal portion of the aorta using a catheter such that the first distal stent portion extends into one of the branched iliac arteries; the catheter may then be withdrawn allowing the prosthesis to re-expand in situ.

It will be appreciated by a person skilled in the art that the prostheses may be introduced to the site of use percutaneously or by "cut down" techniques.

Any of the stents according to this invention may be provided on its external surface with circumferentially spaced wire barbs or hooks adapted to engage in the endoluminal surface of the host artery to resist longitudinal movement or slippage of the stent in use. Typically the barbs or hooks may be disposed on part of the stent which is provided with a fabric graft layer such that in use the points of the artery which are engaged by the barbs or hooks are covered by the fabric graft. It will be appreciated by a person skilled in the art that the trauma to the artery wall caused by the hooks or barbs may cause emboli; the provision of the fabric graft over the barbs or hooks in use will therefore help to prevent the introduction of such emboli into the blood stream. Alternatively, the barbs may be sewn onto the outside surface of the fabric.

The male engaging portion for the first stent may be provided with circumferentially spaced hooks or barbs on its external surface to engage the internal surface of said female cooperating means, thereby to reinforce the connecting means against longitudinal separation of the stents one from the other in the service.

end adapted to contact the proximal stent portion, a distal portion pusher disposed at least partially within the proximal portion pusher and having a proximal end adapted to contact the distal stent portion; and a balloon catheter, having a balloon attached thereto, disposed at least partially within the distal portion pusher.

This invention in another aspect provides a method for delivering a bifurcated endoluminal stent or prosthesis having a proximal portion and a first distal portion into the vasculature at an angeological bifurcation where a blood vessel branches into a first branched vessel and a second branched vessel. The method comprises inserting a first introducer containing the stent or prosthesis into the vasculature to a predetermined delivery location, the first introducer comprising an outer sheath, a proximal portion pusher, and a distal portion pusher; withdrawing the outer sheath of the first introducer while maintaining the proximal portion pusher in a fixed position until the proximal portion of the stent or prosthesis is deployed from the first introducer into the blood vessel; withdrawing the outer sheath and the proximal portion pusher while maintaining the distal portion pusher in a fixed position until the first distal portion of the stent or prosthesis is deployed from the first introducer at least partially into the first branched vessel; and withdrawing the first introducer from the vasculature.

This invention further provides a method for delivering, into the vasculature at an angeological bifurcation where a blood vessel branches into two branched vessels, an endoluminal prosthesis having a proximal stent portion, and a distal stent portion. The method comprises the steps of inserting an introducer containing the prosthesis into the vasculature to a predetermined delivery location, the introducer comprising an outer sheath, a proximal stent portion pusher, a distal stent portion pusher, and a balloon catheter having a balloon attached thereto; inflating the balloon to at least partially block blood flow in the blood vessel; withdrawing the outer sheath of the introducer while

Figure 1b is a front view of another stent which is adapted to be connected to the bifurcated stent of Figure 1a.

Figure 2(a) is a side view of part of the bifurcated stent of Figure 1a opened up to show its construction.

Figure 2(b) is a side view of an exemplary mandrel used to form the part of the bifurcated stent shown in Figure 2(a).

Figure 3 is a side view of another part of the bifurcated stent of Figure 1a opened up to show its construction.

Figure 4(a) is a side view of yet another part of the bifurcated stent of Figure 1a opened up to show its construction.

Figures 4(b)-4(f) are partial exploded views of the exemplary stent of Figure 4(a) illustrating alternative means for securing juxtaposed apices according to the present invention.

Figure 5 is a schematic perspective view of a bifurcated endoluminal prosthesis in accordance with the present invention.

Figure 6 is a schematic view of another bifurcated endoluminal prosthesis in accordance with the present invention.

Figure 7 is a schematic view of yet another bifurcated endoluminal prosthesis in accordance with the present invention.

Figure 8(a) is a cross-sectional view of an exemplary assembled introducer according to the present invention.

Figures 8(b)-8(e) are side views of the component parts of the introducer of Figure 8(a).

Figure 8(f) is a partial cross-sectional view of the introducer of Figure 8(a).

that can be treated using the apparatus and method of the present invention include aneurysm, stenosis, and occlusion.

A bifurcated stent in accordance with the present invention which is indicated at 10 in Figure 1a comprises a wire skeleton which is constructed in four separate parts, namely a proximal part 12, a first frustoconical part 14, a first distal part 16 and a second frustoconical part 18. Said bifurcated stent 10 carries a fabric graft layer (Figures 5, 6, and 7) for use as an endoluminal prosthesis e.g. in the infrarenal portion of a mammalian aorta in juxtaposition with the bifurcation of the common iliac arteries. It will be appreciated, however, that bifurcated stents (with or without fabric graft layers) for use in different parts of the angeological system and for different mammals can be constructed in accordance with the invention by varying the dimensions of the stent accordingly.

Each of the four parts of the bifurcated stent 10 is made in substantially the same way by winding a shape memory nitinol wire, typically nitinol type M wire, onto a mandrel 46.

The construction of the exemplary proximal part 12 of the bifurcated stent 10 is shown in Figures 2(a) and 2(b); nitinol wire type M wire typically having a diameter of 0.46mm (0.018") is wound around mandrel 46 to form a plurality of hoops 20. The winding surface of mandrel 46 is provided with a plurality of upstanding pins 47 disposed in a zig-zag pattern for each of the hoops 20 so that in each hoop 20 the nitinol wire follows a sinuous path to define a plurality of circumferentially spaced apices 22. Each hoop 20 is wound onto mandrel 46 such that the plane of the circumference of each hoop 20 is substantially perpendicular to the longitudinal axis of the mandrel.

When one hoop 20 e.g. the hoop indicated at 20a has been formed, the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel 46 to form the next successive hoop 20b. The stent shown in Figure 2(a) is the stent formed on mandrel 46 shown in Figure

in Figure 4(b). The securing means may also comprise bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in Figure 4(c). Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in Figures 4(d), 4(e), and 4(f) respectively.

The exemplary first and second frustoconical parts 14, 18 of the skeleton shown in the figures are formed in substantially the same way as the proximal part 12 by winding nitinol wire onto a mandrel and then annealing the wire before removing it from the mandrel. As shown in Figure 3, the first and second frustoconical parts 14, 18 are each constituted by three hoops 20 of unit width. The mandrel is tapered such that the proximal end of each of the exemplary frustoconical parts 14, 18 is formed with a diameter of about 12mm and the distal end 32 of each is formed with a diameter of about 9mm. The overall length of each of the exemplary frustoconical parts 14, 18 is about 18mm. The wire used for the frustoconical parts 14, 18 is nitinol type M wire having a diameter of 0.28mm (0.011"). Juxtaposed apices 22 of each of the exemplary frustoconical parts 14, 18 are tied together using 0.03" polypropylene filaments as described above. The first and second frustoconical parts 14, 18 are secured to the distal end 26 of the proximal part 12 of the stent 10 in transversely spaced relation as shown in Figure 1a by securing the apices 22 of the hoop 20 forming the wider proximal end 30 of each of the frustoconical parts 14, 18 to juxtaposed apices 22 of the hoop 20 on the distal end 26 of the proximal part 12.

The exemplary first distal part 16 of the bifurcated stent 10 is formed by winding nitinol type M wire typically having a diameter of 0.28mm (0.011") onto a mandrel to form twelve longitudinally spaced hoops 20 as shown in Figure 4; the exemplary first distal part has an overall length of about 66mm and a uniform diameter of about 9mm. The proximal end 34 of the distal part 16 is secured to the narrower distal end 32 of the first frustoconical part 14 by tying each apex 22 on

The bifurcated endoprosthesis is positioned in the infrarenal section of the aortic artery in juxtaposition with the bifurcation of the common iliac arteries such that the first distal part 16 of the prosthesis extends into one of the common iliac arteries. The catheter is then withdrawn allowing the stent 10 to re-expand towards its configuration as wound on the mandrel in which it was annealed until the stent engages the endoluminal surface of the host artery. The barbs or hooks engage the endoluminal surface of the host artery to resist longitudinal displacement or slipping of the prosthesis in use.

It will be appreciated that when the bifurcated prosthesis is positioned and re-expanded in the fitted position, blood can flow from the aortic artery into the proximal part 12 of the prosthesis from where it can flow into the one common iliac artery through the frustoconical part 14 and the first distal part 16 and also into the other common iliac artery through the second frustoconical part 18.

In cases where it is required to implant a prosthesis in the other common iliac artery a second prosthesis comprising a second stent 40 as shown in Figure 1b can be used. The second stent 40 includes a wire skeleton comprising a proximal frustoconical part 42 and a distal part 44. The distal part 44 of the second stent 40 also may be covered with a tubular graft layer of a biocompatible fabric such, for example, as polyester or polytetrafluoroethylene fabric (Figures 5, 6, and 7).

The frustoconical proximal part 42 is constructed in the same way as the frustoconical parts 14, 18 of the bifurcated stent 10; the distal part 44 is constructed in the same way as the distal part 16 of the bifurcated stent 10. The distal end of the frustoconical proximal part 42 is secured to the proximal end of the distal part 44 by securing juxtaposed apices using polypropylene filaments as described above.

In use, the second prosthesis is compressed radially inwards and is received in a catheter for percutaneous or "cut

the first and second distal frustoconical portions 58, 60. If a prosthesis is required in one or both of the branched arteries, a separate prosthesis comprising a stent of the type shown in Figure 1b referred to above covered with fabric can be connected to the bifurcated prosthesis 50 by inserting and re-expanding the proximal end of such a separate prosthesis in one or both of the distal frustoconical portions 58, 60 of the prosthesis 50 for engagement therein.

Another variant of the present invention is shown in Figure 6 which shows a bifurcated endoluminal prosthesis 70 having a proximal portion 72 which is secured at its distal end 74 to two transversely spaced frustoconical intermediate portions 76, 78.

One of said frustoconical intermediate portions 76 is secured at its distal end to an elongate distal portion 80. The proximal end 82 of the proximal portion 72 is flared radially outwards towards its proximal end 82 to engage the intraluminal surface of the host blood vessel in service. Save for this flared portion, the entire endoprosthesis is covered with a fabric graft layer as shown in Figure 6; said graft layer is carried externally of the wire skeleton and is folded over the distal extremity 84 of the other frustoconical intermediate portion 78 to form an internal lining in said other frustoconical immediate portion 78.

Said other frustoconical intermediate portion 78 constitutes a female cooperating portion in accordance with the present invention which is adapted to receive a male engaging portion of another prosthesis as indicated at 86 in Figure 6. Said other prosthesis 86 includes a frustoconical proximal portion 88 which constitutes the male engaging portion and an elongate distal portion 90. The whole of the other prosthesis 86 is covered with a fabric graft layer as shown in Figure 6. In service, the male engaging portion 88 of the other prosthesis 86 is entered into and engaged with the female cooperating portion 78 of the bifurcated prosthesis 70 in situ in the manner herein before described. The fabric layer on the male engaging portion 88 butts face-to-face on

cylindrical tube slidably contained within distal portion pusher 102. Distal portion pusher 103 is preferably adapted to slide throughout the entire length of proximal portion pusher 102.

Disposed within distal portion 103 is balloon catheter 104. Balloon catheter 104 is adapted to slide within distal portion pusher 103. At the leading end 105 of balloon catheter 104 is nose cone 106. Balloon 107 is attached to balloon catheter 104 between nose cone 106 and proximal end 115 of proximal portion pusher 102.

As shown in Figure 8(g), which is a cross-sectional view of balloon catheter 104 in the direction A-A of Figure 8(f), balloon catheter 104 has a guide wire conduit 104a. Guide wire conduit 104a extends throughout the length of balloon catheter 104 for passing a guide wire (not shown) through introducer 100. In the illustrated embodiment, balloon catheter 104 also includes injection orifice 109 and an injection conduit 109a. Injection conduit 109a connects injection orifice 109 to an injection site 108 at or near the distal end of balloon catheter 104 as shown in Fig. 8(e). Radiopaque liquid may be injected into injection site 108, through injection conduit 109a, out injection orifice 109, and into the vasculature to monitor deployment of the prosthesis.

Also in the illustrated embodiment of Figures 8(f) and 8(g), balloon catheter 104 has an inflation orifice 110 located at a point where balloon 107 is attached to balloon catheter 104. A balloon inflation conduit 110a connects balloon inflation orifice 110 to balloon inflation site 111 (Figure 8(e)). Balloon 107 may be inflated and deflated from balloon inflation site 111 during delivery of the prosthesis.

In an alternative embodiment illustrated in Fig. 9, seals 150, 151 may be disposed around the distal ends 160, 161 of outer sheath 10 and proximal portion pusher 102. Seals 150, 151 may be formed of silicone tubes.

Fig. 10(a) shows an alternative embodiment of introducer 100. As shown in Fig. 10(a), wings 112 and 113 are

prosthesis should preferrably remain in the water during the loading operation.

As supporting stent 10 is compressed beneath the fabric covering of the prosthesis, excess fabric is produced. This excess fabric may simply be pinched together and laid over the compressed prosthesis in longitudinal folds.

Distal portion 16 of the prosthesis in the radially compressed state is then inserted into proximal portion pusher 102. Outer sheath 101 is then pulled over proximal portion 12 of the prosthesis and over proximal portion pusher 102. A thread (not shown) may be attached to the proximal end of proximal portion 12 of the prosthesis and threaded through outer sheath 101. This thread may then be used to pull proximal portion 12 through outer sheath 101. During the loading process, it is important to keep proximal portion 12 and distal portion 16 of the prosthesis properly aligned with outer sheath 101 and proximal portion pusher 102. Marks may be placed on the outside of outer sheath 101 and proximal portion pusher 102 to ensure proper alignment.

Referring again to Fig. 8(f), the prosthesis is inserted such that the outer surface of proximal portion 12 contacts and is radially restrained by outer sheath 101, and the outer surface of distal portion 16 contacts and is radially restrained by proximal portion pusher 102. End 115 of proximal portion pusher 102 longitudinally engages proximal portion 12 of the prosthesis as shown in Fig. 8(f).

Balloon catheter 104 is positioned such that nose cone 106 just clears proximal end 117 of outer sheath 101. The introducer is now in condition for insertion into the patient.

Referring to Fig. 11, introducer 100 is passed through an entry point (not shown) either in the patient's skin (percutaneous operation) or into the vasculature itself which has been surgically exposed ("cut-down" operation). Introducer 100 is inserted over a guide wire 170 into the

Balloon 107 is then deflated to allow blood to flow through proximal portion 12 and out frustoconical portion 18 of the prosthesis. Balloon 107 is withdrawn into the prosthesis until the distal end 118 of nose cone 106 is just above the proximal end of the prosthesis. Balloon 107 is then inflated to seat the prosthesis, which may be provided with barbs (not shown) at its proximal end, against the wall of the aorta, as shown in Fig. 15.

Distal portion pusher 103 is then maintained in a fixed position while outer sheath 101 is withdrawn. Once outer sheath 101 has been withdrawn to the point at which proximal end 117 of outer sheath 101 is flush with proximal end 115 of proximal portion pusher 102, both outer sheath 101 and proximal portion pusher 102 are withdrawn, still maintaining distal portion pusher 103 in a fixed position. Outer sheath 101 and proximal portion pusher 102 are withdrawn until distal portion 16 of the prosthesis is deployed clear of proximal end 116 of distal portion pusher 103 as shown in Fig. 16. Balloon 107 is slowly deflated to allow blood flow to be established through the proximal portion 12 of the prosthesis and out through frustoconical portion 18. Balloon 107 may be used to model distal portion 16 of the prosthesis as necessary by inflating balloon 107 where needed to expand distal portion 16. Balloon 107 is then deflated, and introducer 100 is withdrawn from the vasculature, leaving the guide wire 170 in place, as shown in Figure 17.

Figure 21(a) illustrates an exemplary second introducer 300 used for deploying second distal part 44. Second introducer 300 of the illustrated embodiment comprises cylindrical outer sheath 301 and female Luer lock assembly 310. Second introducer 300 also has hemostasis valve 361 contained within a hub 362 thereof. Cartridge 311 shown in Fig. 21(b) is adapted to be attached to second introducer 300. Cartridge 311 has threaded male Luer lock assembly 312 provided on its proximal end. Cartridge 311 has outer tube 313 which houses inner tube 314.

Cartridge 311 is then lockingly engaged with introducer 300 by mating male Luer lock assembly 310 with female Luer lock assembly 312. Such locking engagement prevents relative movement of cartridge 311 and introducer 300. Preventing relative movement lends stability and reliability to the insertion process that has not heretofore been achieved.

A pusher 315 is then inserted into inner tube 314 of cartridge 311 such that proximal end 317 of pusher 315 longitudinally contacts a distal end of distal portion 44 within inner tube 314. Pusher 315 pushes distal portion 44 through cartridge 311 and into outer sheath 301 of introducer 300. Distal portion 44 is pushed through outer sheath 301, which remains in a fixed position, until distal portion 44 is at proximal end 320 of outer sheath 301 (see Figure 19). Again, radiopaque markers 120 may be used to align distal portion 44 properly with proximal portion 12.

Pusher 302 is held firmly in place, and outer sheath 301 is withdrawn approximately 2 cm. This deploys frustoconical part 42 of distal part 44 inside the frustoconical part 18 as shown in Figure 19. The outer surface of frustoconical part 42 engages the inner surface of frustoconical part 18 such that distal portion 44 is connected to proximal portion 12 to resist longitudinal separation.

Outer sheath 301 may then be withdrawn while maintaining pusher 302 in a fixed position to fully deploy distal portion 44, as shown in Figure 20. If necessary, balloon catheter 104 may be inserted through sheath 301 in order to model distal portion 44. Introducer 301 and guide wires 170, 171 are then removed from the vasculature and the entry points are closed.

The delivery apparatus and method described above are particularly useful in treating an abdominal aortic aneurysm with a bifurcated prosthesis according to the present invention. Other diseases and alternative embodiments of the prosthesis and delivery method will now be described.

The second embodiment of a straight stent that may be used according to this invention is illustrated in Fig. 23. Straight stent 450 includes stent portion 451, constructed of wire loops as described above with reference to stent portions 401 and 402. Stent portion 451 is partially covered by fabric 452. In this embodiment, fabric portion 451 covers and is supported by stent 451, whereas with stent 400, the fabric portion 403 is not supported by a stent.

To treat an abdominal aortic aneurysm that does not extend down over the walls of the iliac arteries, as shown in Figure 24(a), straight stent 400 (or 450) is disposed as illustrated in Figure 26. Proximal stent portion 401 engages the inner walls of the aorta above the aneurysm. Distal stent portion 402 engages the inner wall of the aorta below the aneurysm. Intermediate fabric portion 403 extends across the aneurysm, providing a strong, stable lumen for blood flow through the aorta.

Figure 28 illustrates the delivery apparatus used to implant straight stent 400 in the vasculature. This apparatus is very similar to that described above for the delivery system to be used with the bifurcated stent or prosthesis. Accordingly, like reference numerals refer to the same components.

In the introducer 410 shown in Figure 28, proximal portion pusher 102 engages proximal stent portion 401. Distal portion pusher 103 engages distal stent portion 402.

In use, straight stent 400 is first charged into the introducer by cooling it to temperatures below 10½C, radially compressing it, and inserting it within outer sheath 101, as described above in connection with the bifurcated stent or prosthesis. The remainder of introducer 410 is also assembled as described in connection with introducer 100.

Introducer 410 is passed through an entry point (not shown) over guide wire 411 as shown in Figure 24(a). This insertion may be accomplished using percutaneous or cut-down

In use, straight stent 450 is first charged into introducer 490 by cooling it to temperatures below 10½C, radially compressing it, and inserting it within outer sheath 101, as described above in connection with the bifurcated stent or prosthesis. The remainder of introducer 490 is also assembled as described in connection with introducer 100.

Introducer 490 is passed through an entry point (not shown) over a guide wire 411 as shown in Figure 30. This insertion may be accomplished using percutaneous or cut-down techniques. Introducer 490 is then inserted to the desired delivery location.

In the aorta, introducer 490 is positioned and balloon 107 is inflated above the renal arteries in the same manner as described above in connection with the bifurcated stent and as illustrated in Fig. 31.

While maintaining attached proximal portion pusher 102 and distal portion pusher 103 in a fixed position, outer sheath 101 is withdrawn until proximal portion 451 of stent 450 emerges from outer sheath 101 as shown in Fig. 32. Using a radiopaque marker 420 disposed on the proximal end of the proximal portion 451, stent 450 is optimally aligned within the aorta. Outer sheath 101 is then completely withdrawn until stent 450 is deployed into the aorta as shown in Fig. 33.

Balloon 107 is then deflated and withdrawn inside proximal portion 451 where balloon 107 is re-inflated to seat the stent 450, as shown in Figure 34. Balloon 107 is then withdrawn, along with the introducer 490 as described above, and the entry point is closed.

The angeological disease of occlusion is the blockage of an artery resulting from a buildup or clot of soft thrombus. There are two types of occlusions that can occur at the aorta-iliac bifurcation. The first is infrarenal occlusion. In this case, the blockage extends in the aorta from just below the renal arteries into the iliac arteries.

bifurcated endoluminal stent according to the present invention is then implanted at the bifurcation site. This stent is the same as that described above for treatment of an abdominal aortic aneurysm. To treat the stenosis, however, it is not necessary to cover the stent with a fabric, thus creating a prosthesis. Because restenosis is rare at the bifurcation site, there is no need to isolate the blood flowing in the lumen from the walls of the arteries.

The delivery system used to implant the bifurcated endoluminal stent used to treat stenosis is the same as that illustrated in Figure 8 except that balloon 107 is not required. Because there is no fabric around the stent to be affected by blood flow in the arteries and cause migration of the bifurcated stent, it is not necessary to block the blood flow with the balloon. Otherwise, the delivery system for implanting the bifurcated stent to treat stenosis is the same as that for implanting the bifurcated prosthesis to treat abdominal aortic aneurysm.

Similarly, with the exception of the steps involving inflation of balloon 107 to block blood flow, the method of delivering the bifurcated endoluminal stent to treat stenosis is the same as that described above for delivering the bifurcated endoluminal prosthesis to treat abdominal aortic aneurysm.

7. An introducer for delivering a bifurcated endoluminal stent or prosthesis as claimed in claim 2, wherein said balloon catheter has a proximal end with a nose cone attached thereto.

8. An introducer for delivering into the vasculature at an angeological bifurcation where a blood vessel branches into two branched vessels, an endoluminal prosthesis having a proximal stent portion and a distal stent portion, said introducer comprising:

(a) a tubular outer sheath;

(b) a proximal portion pusher disposed at least partially within said outer sheath and having a proximal end adapted to contact said proximal stent portion;

(c) a distal portion pusher disposed at least partially within said proximal portion pusher and having a proximal end adapted to contact said distal stent portion; and

(d) a balloon catheter, having a balloon attached thereto, disposed at least partially within said distal portion pusher.

9. An introducer for delivering an endoluminal stent into the vasculature at an angeological bifurcation where a blood vessel branches into two branched vessels, said introducer comprising:

(a) a tubular outer sheath;

(b) a proximal portion pusher disposed at least partially within said outer sheath and having a proximal end adapted to contact a distal end of said stent; and

(c) a distal portion pusher disposed at least partially within said proximal portion pusher and secured to said proximal portion pusher such that proximal ends of said distal portion pusher and said proximal portion pusher are flush with one another.

10. A method for delivering a bifurcated endoluminal stent or prosthesis having a proximal portion and

second distal portion extends at least partially into said second branched vessel; and

(c) withdrawing said second introducer from the vasculature.

12. A method for delivering a bifurcated endoluminal stent or prosthesis as claimed in claim 10 wherein said first introducer further comprises a balloon catheter having a balloon attached thereto and said method further comprises the step of inflating said balloon to at least partially block blood flow in said blood vessel after inserting said first introducer into the vasculature.

13. A method for delivering, into the vasculature at an angeological bifurcation where a blood vessel branches into two branched vessels, an endoluminal prosthesis having a proximal stent portion, and a distal stent portion, said method comprising the steps of:

(a) inserting an introducer containing said prosthesis into the vasculature to a predetermined delivery location, said introducer comprising an outer sheath, a proximal stent portion pusher, a distal stent portion pusher, and a balloon catheter having a balloon attached thereto;

(b) inflating said balloon to at least partially block blood flow in said blood vessel;

(c) withdrawing said outer sheath of said introducer while maintaining said proximal stent portion pusher in a fixed position until said proximal stent portion of said prosthesis is deployed from said introducer into said blood vessel;

(d) withdrawing said outer sheath and said proximal stent portion pusher while maintaining said distal stent portion pusher in a fixed position until said distal stent portion of said prosthesis is deployed from said introducer into said blood vessel; and

18. A method of treating an angeological disease at a bifurcation site where a blood vessel branches into a first branched vessel and a second branched vessel as claimed in claim 16 wherein said disease is an occlusion.

19. An endoluminal stent comprising a plurality of hoops which are axially displaced in a tubular configuration along a common axis, each of said hoops

(a) being formed by a substantially complete turn of a sinuous wire having apices, and

(b) having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of said stent;

wherein apices of adjacent hoops are juxtaposed to one another, and at least two juxtaposed apices are connected by a securing means.

20. A stent as recited in claim 19 in combination with one or more additional stent segments.

21. A stent as recited in claim 20 wherein at least one of said additional stent segments comprises a plurality of hoops which are axially displaced in a tubular configuration along a common axis, each of said hoops

(a) being formed by a substantially complete turn of a sinuous wire having apices, and

(b) having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of said stent;

wherein apices of adjacent hoops are juxtaposed to one another, and at least two juxtaposed apices are connected by a securing means.

22. A stent as recited in claim 20 wherein said one or more additional segments are axially aligned with one another.

23. A stent as recited in claim 20 wherein said one or more additional segments are secured to one another by

34. An endoluminal stent as claimed in claim 19 wherein said securing means is a ring.

35. An endoluminal stent as claimed in claim 19 wherein said securing means is a staple.

36. An endoluminal stent as claimed in claim 19 wherein said securing means is wire twisted into loop.

37. An endoluminal stent as claimed in claim 36 wherein said wire is nitinol.

38. An endoluminal stent as claimed in claim 19 wherein said securing means is bead of thermoplastic material.

39. An endoluminal stent as claimed in claim 19 wherein the plane of the circumference at each longitudinal end of the stent is square to the longitudinal axis of the stent.

40. An endoluminal stent as claimed in claim 19 wherein said stent is at least partially covered in fabric.

41. An endoluminal stent as claimed in claim 31 wherein said wire is nitinol.

42. A method of making an endoluminal stent having a plurality of hoops which are axially displaced in a tubular configuration, each of said hoops being formed by a substantially complete turn of a sinuous wire with apices and having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of the stent, said method comprising the steps of:

(a) winding a wire in a zig-zag pattern around a mandrel having a plurality of upstanding pins defining said zig-zag pattern to form a first hoop having apices and a circumference that lies in a plane substantially perpendicular to the longitudinal axis of said mandrel;

(b) longitudinally displacing said wire with respect to the axis of said mandrel;

48. A method as claimed in claim 47 wherein said tube is platinum.

49. A method as claimed in claim 47 wherein said tube is gold.

50. Apparatus for delivering an endoluminal stent or prosthesis into the vasculature comprising:

(a) an introducer having a first portion of a lock fitting on a distal end thereof; and

(b) a cartridge having an inner tubular member containing said stent or prosthesis in a compressed state, an outer sheath, and a second portion of said lock fitting;

wherein said first portion of said lock fitting on said introducer mates with said second portion of said lock fitting on said cartridge to prevent relative movement of said introducer and said cartridge.

51. Apparatus as claimed in claim 50 wherein said lock fitting is a Luer lock.

52. Apparatus as claimed in claim 50 further comprising a hemostasis valve on said introducer and a pusher adapted to push said compressed stent or prosthesis through said cartridge, through said introducer, and into the vasculature.

53. A bifurcated prosthesis comprising:

a bifurcated stent having a proximal stent portion adapted to be disposed within a blood vessel in juxtaposition with a bifurcation, a first distal stent portion adapted to extend across the bifurcation into a first branched blood vessel, and a second distal stent portion adapted to allow blood to flow from the proximal portion into a second branched vessel,

a tubular graft layer formed from a biocompatible fabric disposed in juxtaposition with said bifurcated stent, and

61. A bifurcated stent as claimed in claim 60 wherein each hoop comprises a substantially complete turn of the wire.

62. A bifurcated stent as claimed in claim 60 wherein the plane of the circumference of the hoop at each longitudinal end of the stent is square to the longitudinal axis of the stent.

63. A stent as claimed in claim 60 further comprising securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors.

64. A bifurcated stent as claimed in claim 63 wherein said securing means comprises a loop element to tie the juxtaposed apices together.

65. Stent apparatus for use in juxtaposition with an angeological bifurcation; said apparatus comprising a first bifurcated stent comprising a proximal stent portion adapted to be disposed within a blood vessel in juxtaposition with a bifurcation, a first distal stent portion adapted to extend across the bifurcation into one of the branched blood vessels, and a second distal stent portion adapted to allow blood to flow from the proximal portion into the other branched vessel; and a second stent adapted to extend in the other branched blood vessel; wherein said second distal stent portion comprises a female cooperating portion and said second stent comprises a male engaging portion adapted to engage said female cooperating portion; the arrangement being such that, in use, said first bifurcated stent can be joined in situ to the second stent.

66. Stent apparatus as claimed in claim 65 wherein the proximal end of said first stent is flared radially outwardly towards its extremity to engage the endoluminal surface of the blood vessel, thereby to resist longitudinal movement of the first stent in service.

67. A bifurcated prosthesis comprising:

service the inter-engagement of the male engaging portion and the female cooperating portion so as the resist longitudinal separation of the two stents one from the other.

73. A stent joining means as claimed in claim 72 wherein said first stent includes a proximal male engaging portion.

74. A stent joining means as claimed in claim 72 wherein said second stent includes a distal female cooperating portion.

75. A stent joining means as claimed in claim 72 wherein said male engaging portion is flared radially outwardly towards its extremity.

76. A stent joining means as claimed in claim 72 wherein the male engaging portion comprises a frustoconical wall which flares outwardly towards its longitudinal extremity.

77. A stent joining means as claimed in claim 72 wherein the female engaging portion comprises a frustoconical wall which tapers radially inwardly towards its longitudinal extremity.

78. A stent joining means as claimed in claim 72 wherein said male engaging portion and said female cooperating portion are substantially untapered.

79. A stent joining means as claimed in claim 72 wherein said male engaging portion and said female cooperating portion are substantially cylindrical.

80. A stent joining means as claimed in claim 72 wherein said male engaging portion is resiliently compressible in a radially inwards direction such that in a radially compressed state the male engaging portion is capable of self re-expansion to engage in the female cooperating portion.

81. A stent joining means as claimed in claim 72 wherein each of said first and second stents is resiliently compressible.

89. An endoluminal stent formed within the vasculature of a body according to a process comprising the steps of inserting an end of a first stent portion at least partially into an end of a second stent portion, and allowing said end of said first stent portion to expand and contact said end of said second stent portion.

90. An endoluminal prosthesis comprising a stent as claimed in claim 89, and a tubular graft layer formed from a bio-compatible fabric disposed in juxtaposition with said stent.

91. A bifurcated prosthesis as claimed in claim 67 wherein said graft layer is disposed on the external surface of the stent.

FIG. 2A

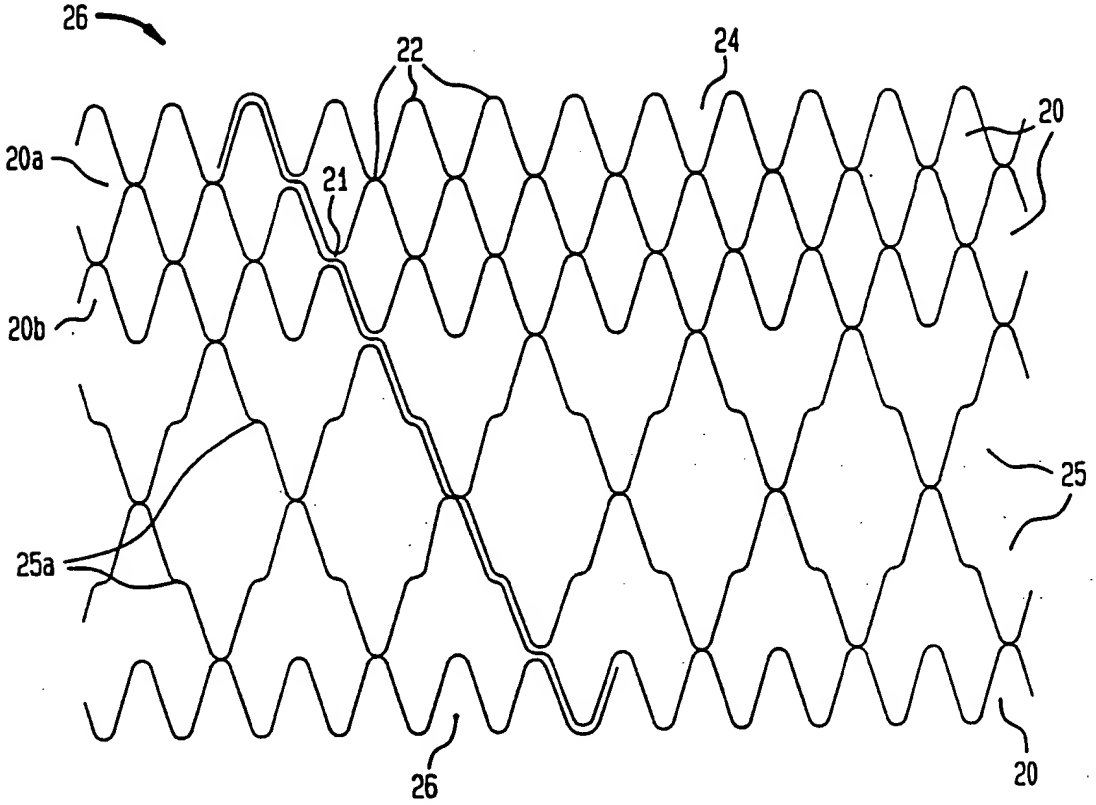


FIG. 2B

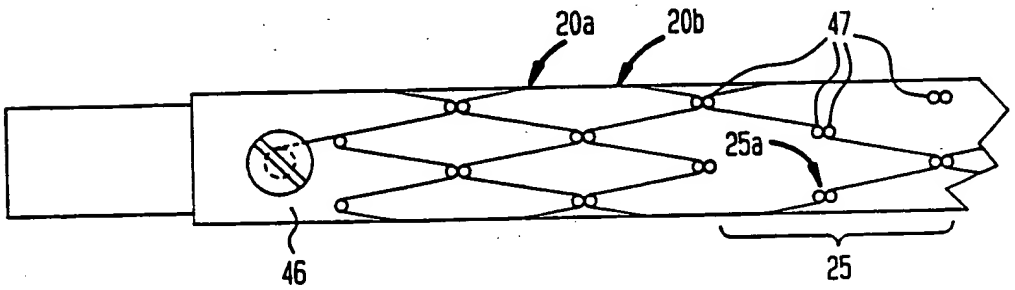


FIG. 4F

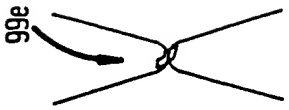


FIG. 4E

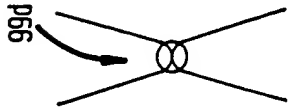


FIG. 4D

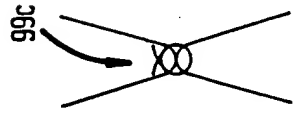


FIG. 4C

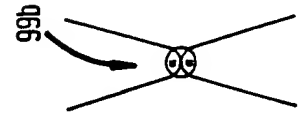
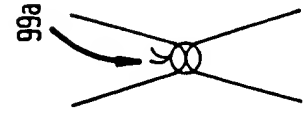


FIG. 4B



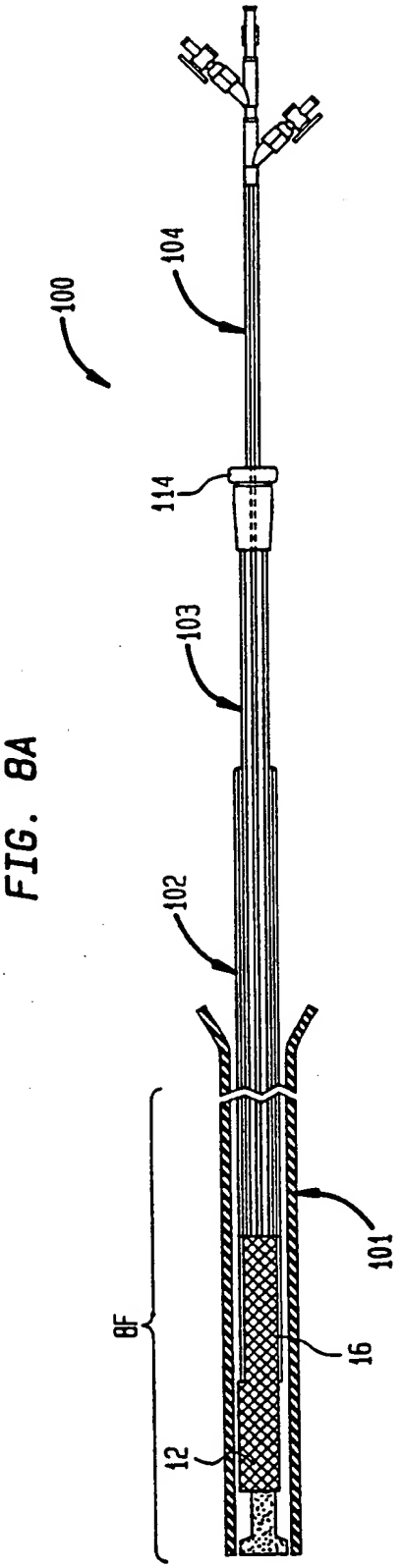


FIG. 8A

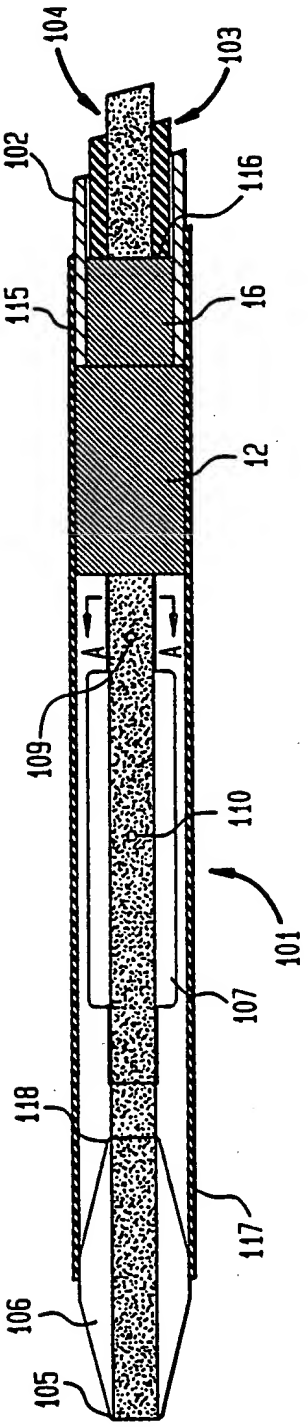

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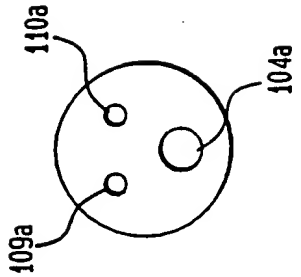
FIG. 8F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109a

FIG. 8G

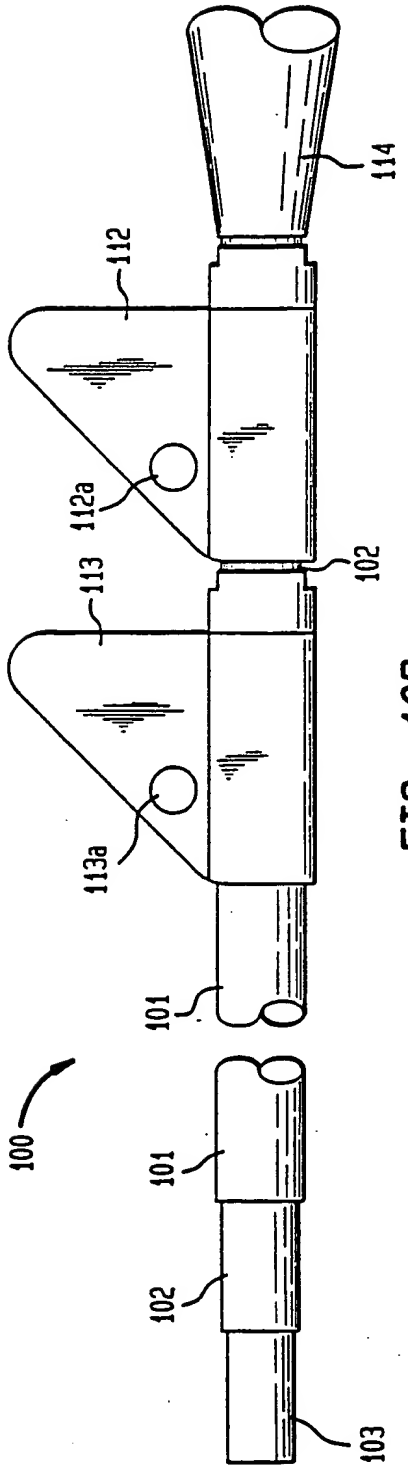

FIG. 10A

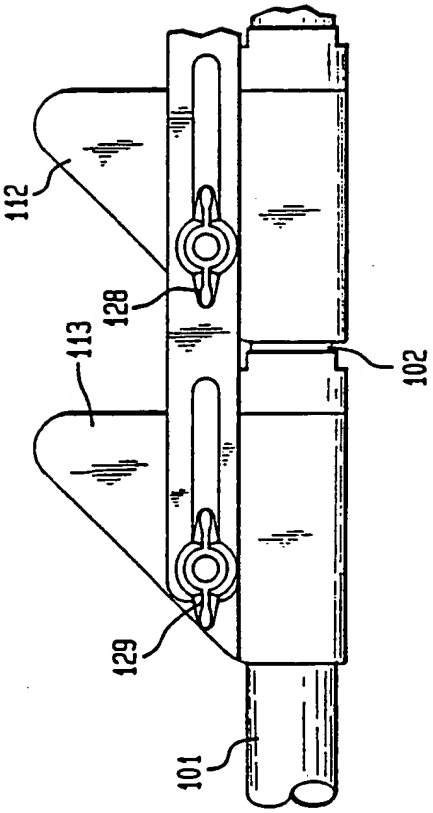

FIG. 10B

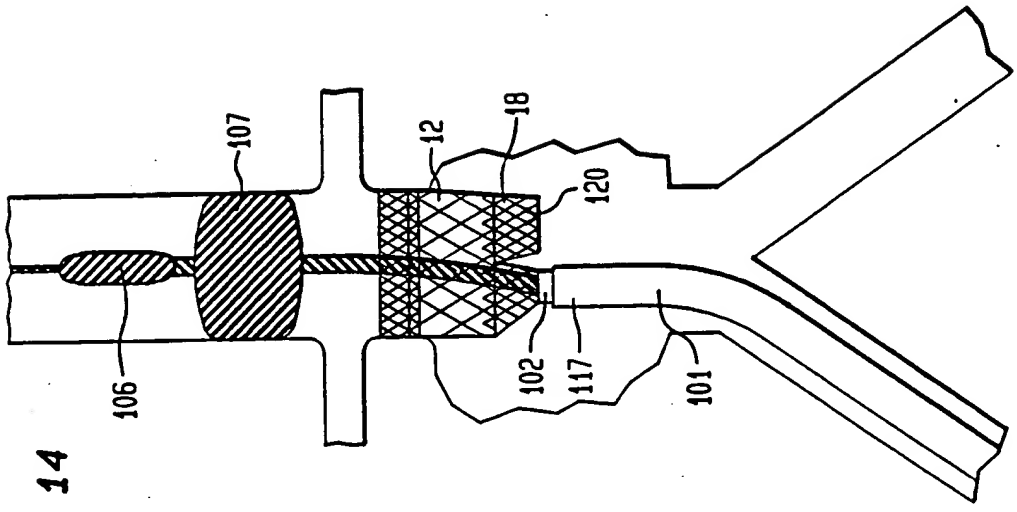

FIG. 14

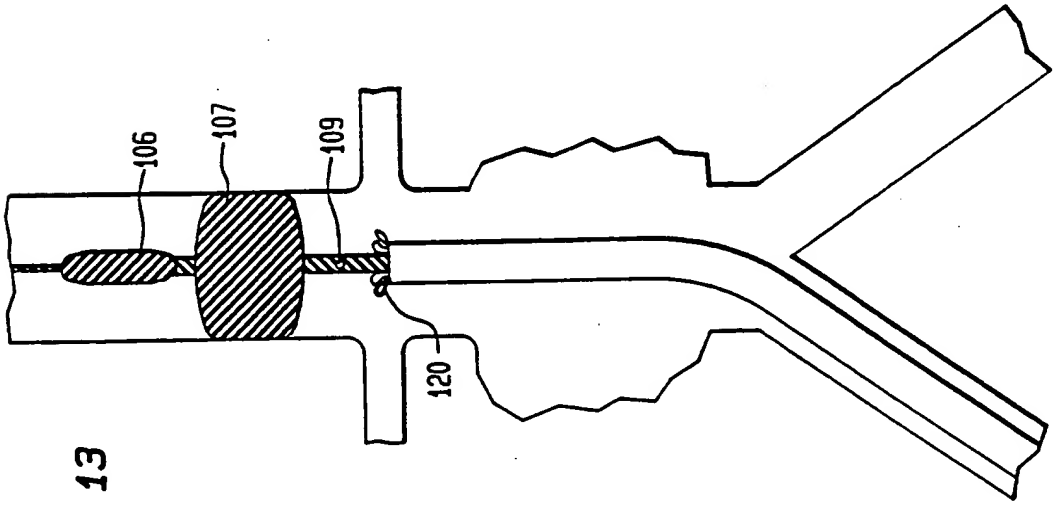

FIG. 13

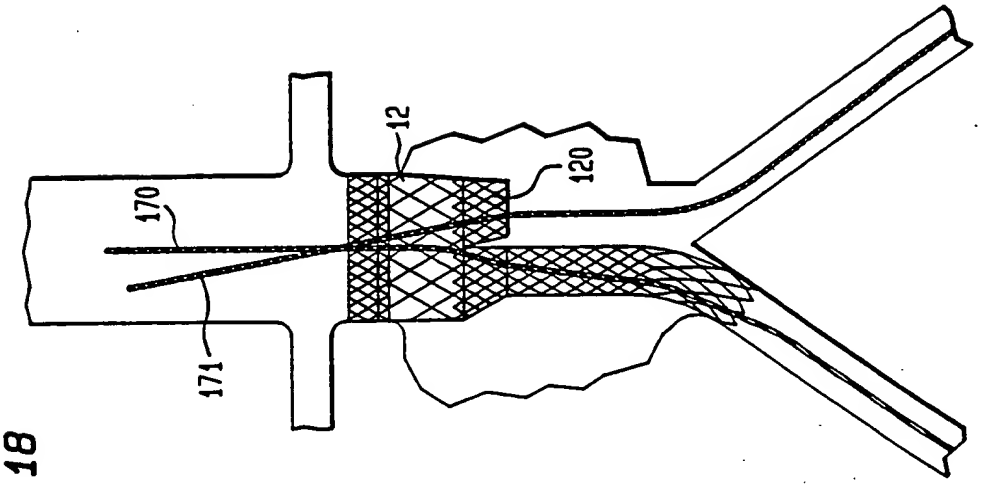

FIG. 18

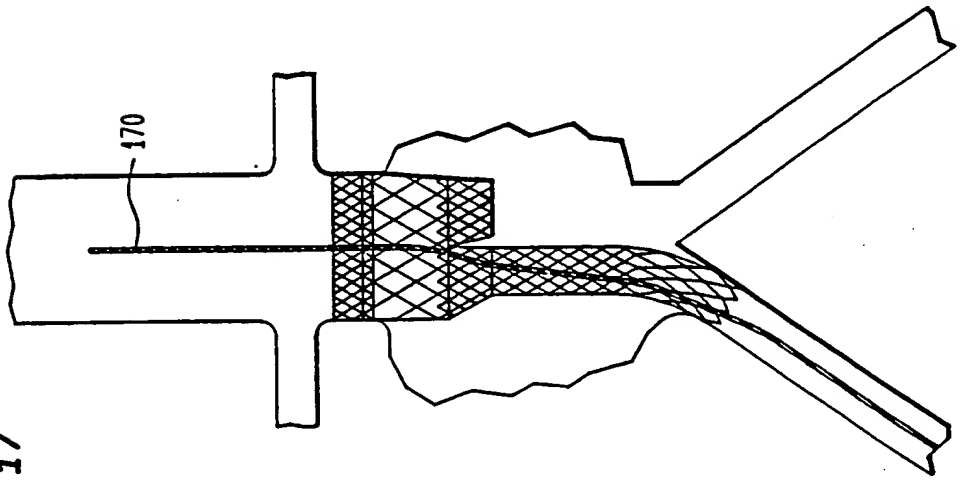

FIG. 17

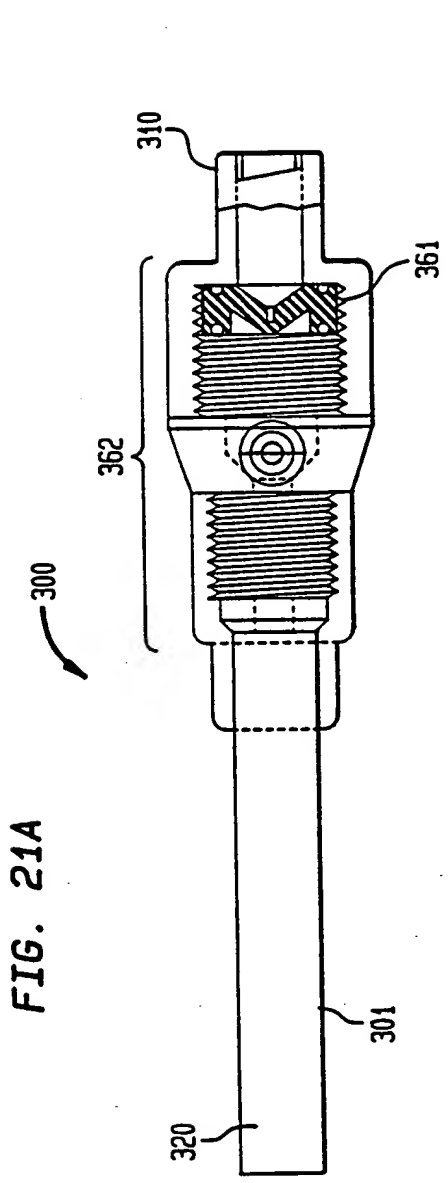

FIG. 21A

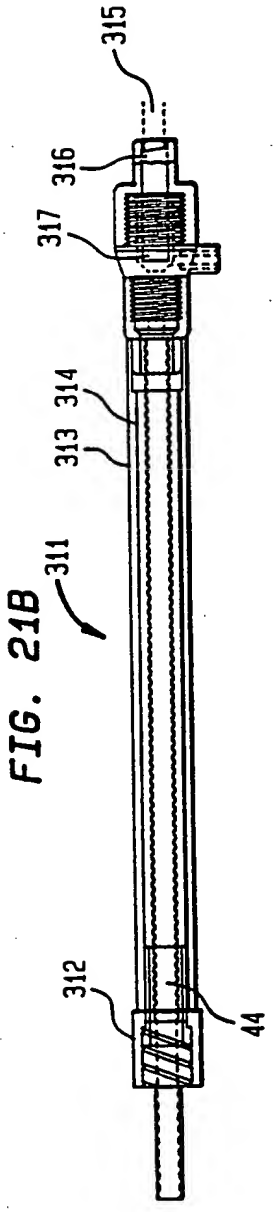

FIG. 21B

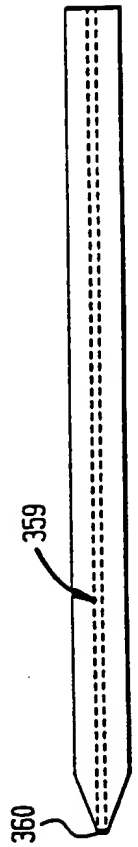

FIG. 21C

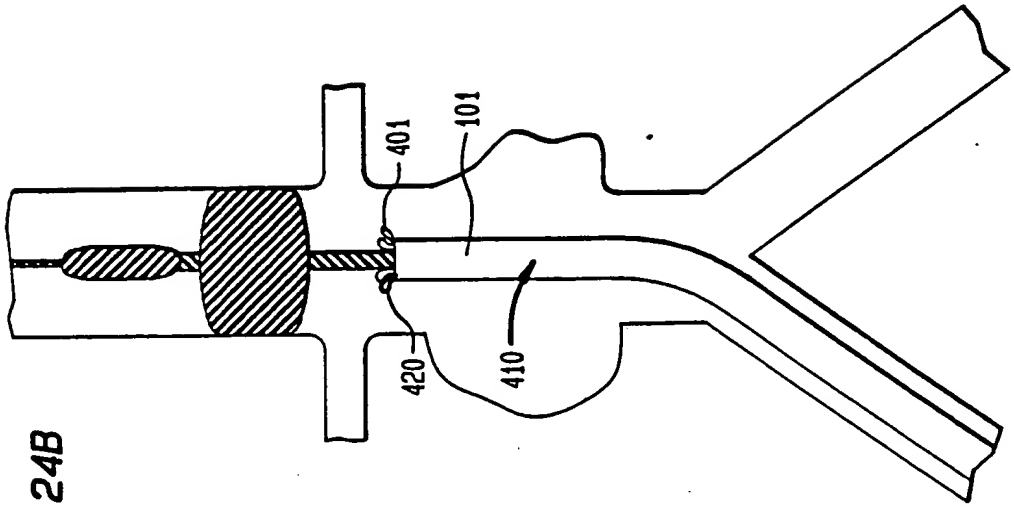

FIG. 24B

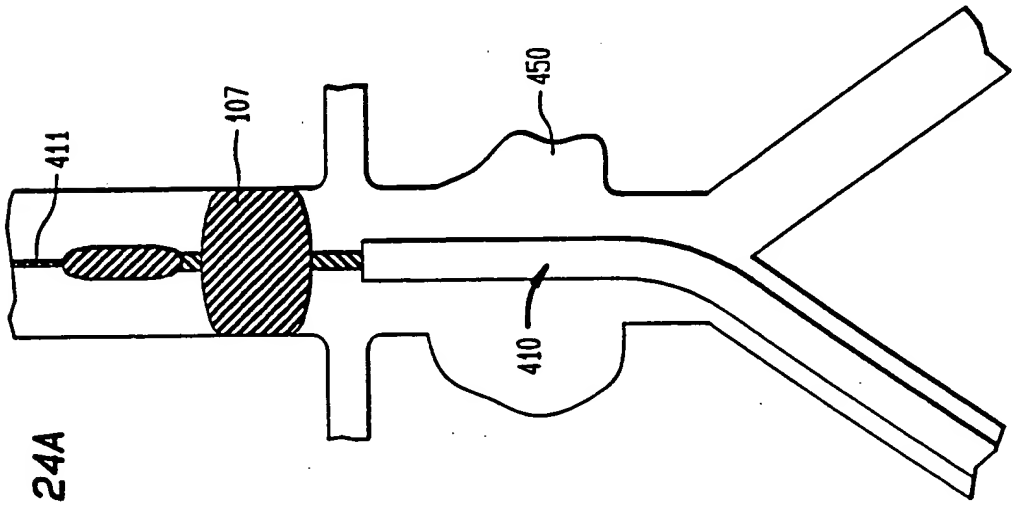

FIG. 24A

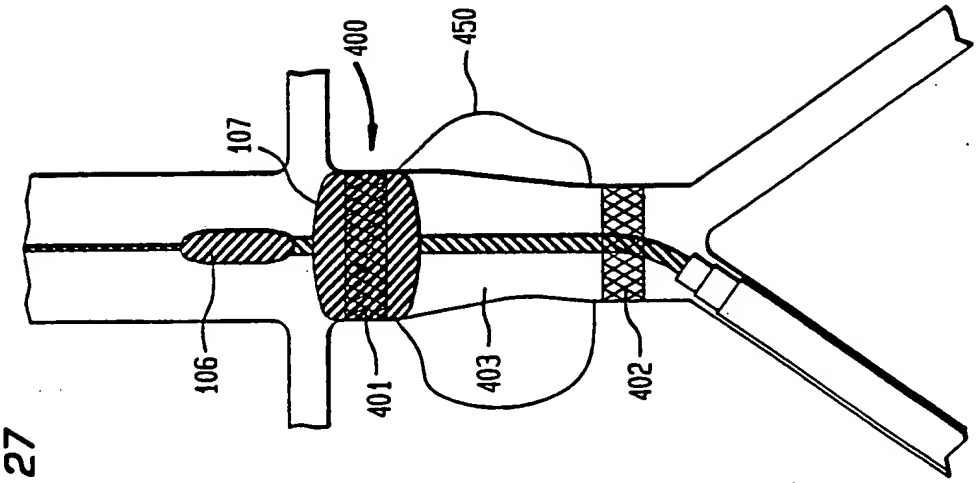

FIG. 27

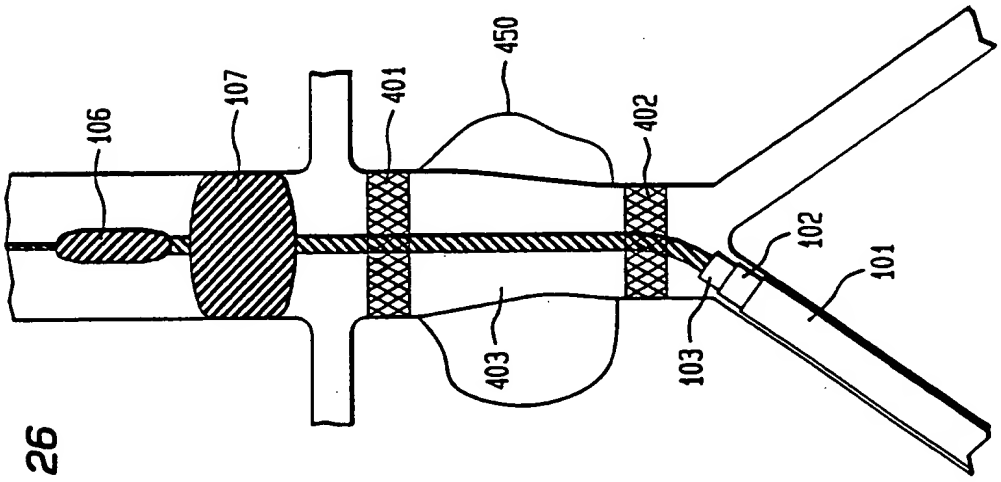

FIG. 26

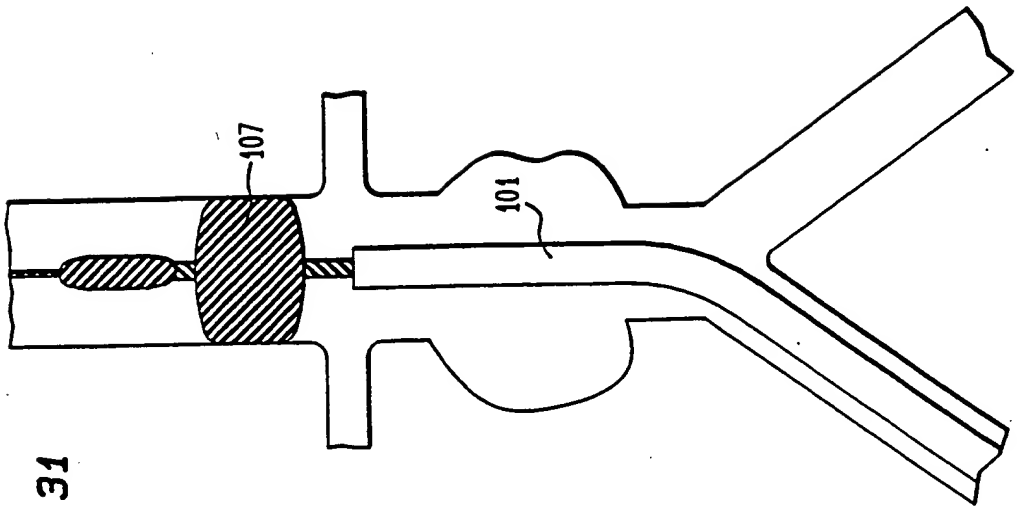

FIG. 31

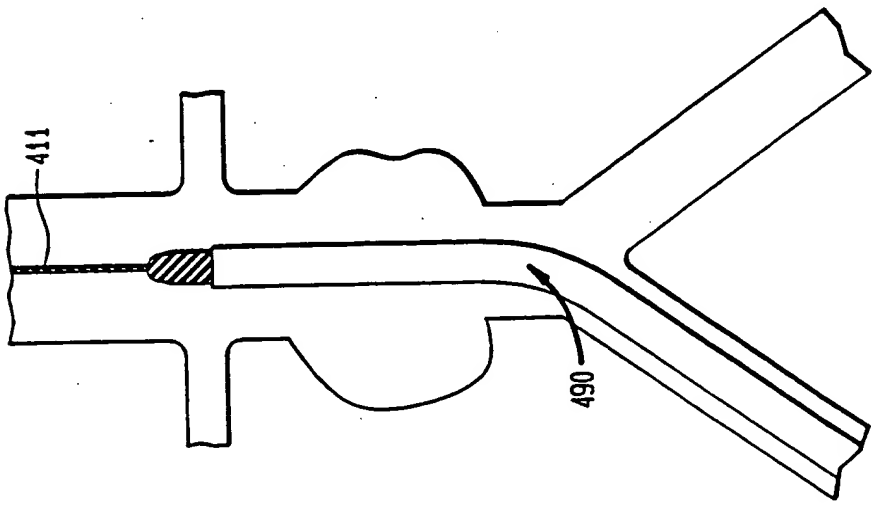

FIG. 30

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 95/01466

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,89 08433 (H.M. LAZARUS) 21 September 1989	1,2,5-8
Y	see the whole document	3
A		40,50, 53-55

X	EP,A,0 508 473 (ENDOVASCULAR TECHNOLOGIES) 14 October 1992	53-55
Y	see the whole document	3
A		50-52

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 July 1995	28.07.95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Wolf, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/01466

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10-18, 43-49, 88-90
because they relate to subject matter not required to be searched by this Authority, namely:
see Rule 39.1 (iv) PCT. Method for treatment of the human body by surgery.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 95/01466

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0423916		JP-C-	1865230	26-08-94
		JP-A-	3133446	06-06-91
EP-A-0579523	19-01-94	FR-A-	2693366	14-01-94
US-A-4562596	07-01-86	US-A-	4617932	21-10-86
EP-A-0551179	14-07-93	US-A-	5316023	31-05-94
		AU-B-	658253	06-04-95
		AU-A-	3108793	29-07-93
		CA-A-	2085918	09-07-93
		JP-A-	5344989	27-12-93
		ZA-A-	9210122	03-08-93
DE-A-4303181	11-08-94	AU-B-	5970194	29-08-94
		WO-A-	9417754	18-08-94